

**REMARKS**

Claims 1-12 and 14-51 are pending in this application. Of these claims, Claims 17-29 and 33-35 have been previously withdrawn. Claims 1-12, 14-16, 30-32, 36-46 and 48-51 are rejected. Claim 47 is allowed. Applicant amends Claims 1 and 30 and respectfully requests reconsideration and favorable action in this case in view of the following remarks.

**Allowable Subject Matter**

Applicant appreciates the Examiner's indication that Claim 47 is allowed.

**Claim Rejections - 35 USC § 103**

Claims 1-9, 30, 32, 36, and 38-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Goble* in view of U.S. Patent No. 5,338,197 to Kwan (“*Kwan*”). Applicant respectfully traverses these rejections for the reasons set forth below.

Claims 1, 30, and 36 each include limitations generally directed to a screw portion of a bone anchor including a rounded interior surface enclosing a protrusion recess. The rounded interior surface includes a single, continuous recess thread extending a majority of a length of the protrusion recess. The recess thread is configured to rotatably retain a threaded component at least partially in the protrusion recess.

The combination of *Goble* and *Kwan* relied on by Examiner as teaching these limitations is improper because *Goble* teaches away from the modification proposed by Examiner. MPEP § 2141.02(VI). *Goble* discloses “a bone fixation system to provide a system for coupling bone ends together.” (Col. 2, lines 28-29) (emphasis added). As repeatedly argued by Applicant, *Goble* could not be modified to include a single, continuous recess thread configured to rotatably retain a threaded component. If such modification were made, in order to pull the broken bone end faces together into close fitting engagement (*Goble*, Col. 4, lines 33-35), one bone end would have to be rotated with respect to the other bone end. Rotation to join broken bone ends is not feasible because the joined bone portions are likely not to align in correct anatomical position after the engagement. Accordingly, the modification of *Goble* to include the threaded passageway 60 of *Kwan* is improper and cannot be used to obviate Claims 1, 30, and 36, which recite a single, continuous recess

thread extending a majority of a length of a protrusion recess, the recess thread being configured to rotatably retain a threaded component at least partially within the protrusion recess.

Furthermore, Examiner's explanation as to why it would have been obvious to modify *Goble* with the teaching of *Kwan* does not meet his burden. The U.S. Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex, Inc.* reiterated the requirement that Examiners provide an explanation as to why the claimed invention would have been obvious. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). The analysis regarding an apparent reason to combine the known elements in the fashion claimed in the patent at issue "should be made explicit." *KSR*, 127 S.Ct. at 1740-41. "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* at 1741 (internal quotations omitted). Moreover, according to the PTO's own rules, "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57526, 57528-29 (Oct. 10, 2007) (internal citations omitted).

"The [obviousness] analysis is objective: 'Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined.'" *Id.* (citing *Graham v. John Deere*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459 (1966)). While not a rigid test, a showing of a "teaching, suggestion, or motivation" to combine or modify prior art provides helpful insight in determining whether it would have been obvious to combine references. *Id.* "A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *Id.* (citing *Graham*, 383 U.S. at 36).

In the present case, the Office Action contends that it would be obvious to modify *Goble* with the teachings of *Kwan* “to have better control and orientation when installing the anchor.” (Office Action p. 4). Such a statement does not rationally support Examiner’s obviousness contention and is certainly not sufficient to meet Examiner’s burden to provide an explanation as to why the claimed invention would have been obvious. *KSR Int’l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). It should be clear from *Goble* and *Kwan* that the internally threaded passageway 60 of *Kwan* would not affect the orientation or the installation of female connector 13 of *Goble* in any way.

Moreover, the Examiner has not clearly articulated the scope and content of the prior art, the differences between the prior art and the claims at issue, or the level of ordinary skill in the art. The Examiner has also not shown a teaching, suggestion, or motivation to modify *Goble* with the teaching of *Kwan* in the manner suggested. Rather, the Examiner’s asserted motivation is comprised merely of conclusory statements and personal opinion that do not even rationally support his position. The Supreme Court is clear that this is insufficient to establish obviousness: “Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_, No. 04-1350 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Accordingly, Applicant respectfully requests that the rejections of Claims 1, 30, and 36, and their dependent claims be withdrawn.

Claim 10 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of *Goble* and *Kwan* and further in view of U.S. Patent No. 5,662,683 to Kay (“*Kay*”). Claims 11, 31 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of *Goble* and *Kwan* and further in view of U.S. Patent No. 6,333,971 to McCrory (“*McCrory*”). Applicant respectfully traverses these rejections for the reasons set forth below.

Claims 10-11, 31, and 37 each depend from Claims 39, 40, and 41 respectively and incorporate all the respective limitations thereof. In rejecting these claims, the Office Action

relies on the combination of *Goble* and *Kwan* as disclosing each of the limitations of each Claim's respective base claims. As discussed above, the combination of *Goble* and *Kwan* is improper and does not disclose, teach, or suggest each of the limitations of the respective base claims, and neither *Kay* nor *McCrory* cures this deficiency. Therefore, Applicant contends that Claims 10-11, 31, and 37 are allowable for at least the same reasons discussed above with regard to their respective base claims. Accordingly, Applicant respectfully requests that the rejections of Claims 10-11, 31, and 37 be withdrawn.

Claim 14 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of *Goble* and *Kwan*. Applicant respectfully traverses these rejections for the reasons set forth below.

Claim 14 depends from Claim 12 and incorporates all the limitations thereof. In rejecting Claim 14, the Office Action relies on the combination of *Goble* and *Kwan* as disclosing each of the limitations Claim 12. As discussed above, the combination of *Goble* and *Kwan* is improper and does not disclose, teach, or suggest each of the limitations of Claim 12, and the Examiner's material obviousness arguments (with which Applicant does not agree) do not cure this deficiency. Accordingly, Applicant respectfully requests that the rejection of Claim 14 be withdrawn.

#### **Claim Rejections - 35 USC § 102**

Claims 12, 14-16 and 43-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,417,692 to *Goble et al.* ("*Goble*"). Applicant respectfully traverses these rejections for the reasons set forth below.

Claim 12 includes limitations directed to a driver recess that is configured to retain an insert positioned at least partially within a threaded protrusion recess of the protrusion of the bone anchor. The insert provides a friction fit between the driver and the bone anchor during insertion of the bone anchor.

The Office Action contends that these limitations are "considered a functional limitation of the device." (Office Action p. 6). Applicant respectfully disagrees that these

limitations are merely functional. However, even assuming Claim 12 includes functional limitations, the law is clear that “[t]here is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper.” *In re Swinehart*, 169 USPQ 226 (CCPA 1971); MPEP § 2173.05(g). If functional language defines one or more structural attributes of an element, then the Examiner must give that language patentable weight.<sup>1</sup> See MPEP § 2173.05(g).

Here, Applicant has properly defined a structural attribute of the driver recess, namely that it is configured to retain an insert positioned at least partially within a threaded protrusion recess of the protrusion of the bone anchor. *Goble* does not disclose, teach, or suggest the structural elements of the driver recess of Claim 12. Rather, *Goble* teaches a turning tool 23 of *Goble* has a "cavity formed therein whose interior wall is sided, like that of the sided tool engaging section 22, and is for making contact therewith to transfer tool 23 turning into member 11 or 12." (Col. 7, lines 38-41). *Goble* does not state that the tool 23 is configured to retain an insert. Accordingly, *Goble* does not disclose, teach, or suggest a driver recess configured to retain an insert positioned at least partially within a threaded protrusion recess of the protrusion of the bone anchor to provide a friction fit between the driver and the bone anchor during insertion of the bone anchor.

For at least this reason, Applicant respectfully contends that *Goble* does not disclose, teach, or suggest each of the limitations of Claim 12. Accordingly, Applicant respectfully requests that the rejections of Claim 12, and Claims 16 and 43-46, which depend therefrom, be withdrawn.

Claim 15 includes limitations directed to a distance between a driver edge and a rim that is approximately equal to a distance between a shoulder of a bone anchor and an end of a protrusion such that when the rim contacts the surface of the bone during insertion, the end of the protrusion will be approximately level with the surface of the bone.

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<sup>1</sup> See e.g., MPEP §2173.05(g) (stating that “limitations such as ‘members adapted to be positioned’ and ‘portions . . . being resiliently dilatable whereby said housing may be slidably positioned’ serve[d] to precisely define present structural attributes of interrelated component parts of the claimed assembly.”)

The Office Action does not even cite to a portion of *Goble* that discloses these elements of Claim 15. Rather, the Office Action merely states, without any support, that “[t]his also has a distance that is approximately equal to the distance between the shoulder of the bone anchor and the end of the protrusion.” (Office Action p. 3). Applicant respectfully disagrees. The sections of *Goble* that discuss the driver 23 do not disclose, teach, or suggest a distance between the driver edge and the rim of the driver that is approximately equal to a distance between the shoulder of the bone anchor and an end of the protrusion. (Col. 7, lines 34-41 and lines 56-61).

For at least this reason, Applicant respectfully contends that *Goble* does not disclose, teach, or suggest each of the limitations of Claim 15, and therefore the rejection of Claim 15 should be withdrawn.

*Goble* also fails to disclose many limitations of Applicant’s dependent claims. For example, Claim 43 includes limitations directed to an insert being retained in the driver recess. The insert is positioned at least partially within a threaded protrusion recess of the protrusion of the bone anchor to provide a friction fit between the driver and the bone anchor during insertion of the bone anchor. The Office Action contends that “the bottom portion of the tip (the tapered bottom portion of 23) forms a rim outside of a second portion, which may be considered 15 (also an insert)” discloses these limitations. (Office Action p. 2). Applicant respectfully disagrees. Element 15 of *Goble* is a hollow cylinder of male connector 14. (*Goble*, Col. 6, lines 4-12). While male connector 14 may ultimately be received by cylindrical cavity 19 of the female connector, it has no function with respect to installation of either male connector 14 or female connector 13. Also, hollow cylinder 15 is not retained in a recess of tool 23 and positioned in a protrusion recess of female connector 13 to provide a friction fit between tool 23 and female connector 13 during installation. Accordingly, Applicant respectfully contends that Claim 43 is allowable over *Goble* for at least this additional reason.

Claim 42 includes limitations directed to a distance between a driver edge and a rim that is approximately equal to a distance between a shoulder of a bone anchor and an end of a protrusion such that when the rim contacts the surface of the bone during insertion, the end of

the protrusion will be approximately level with the surface of the bone. Accordingly, Applicant contends that Claim 42 is patentably distinguishable from *Goble* for at least reasons analogous to those discussed above with regard to Claim 15.

Claim 42 also includes limitations directed to a silicon insert being retained in the driver recess. The insert is positioned at least partially within a threaded protrusion recess of the protrusion of the bone anchor to provide a friction fit between the driver and the bone anchor during insertion of the bone anchor. Accordingly, Applicant contends that Claim 42 is patentably distinguishable from *Goble* for at least additional reasons analogous to those discussed above the regard to Claim 43.

**CONCLUSION**

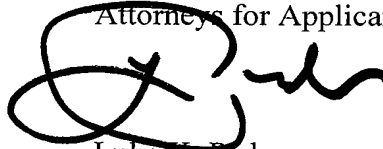
Applicant has made an earnest attempt to place this case in condition for immediate allowance. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests allowance of all pending claims.

The Commissioner is hereby authorized to charge the amount of \$120.00 as payment of a one-month extension fee. No other fee is believed to be due. However the Commissioner is hereby authorized to charge any other fees or credit any overpayments to Deposit Account No. 02-0384 of BAKER BOTTS L.L.P.

If there are matters that can be discussed by telephone to further the prosecution of this application, Applicant respectfully requests that the Examiner call his attorney at the number listed below.

Respectfully submitted,

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